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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,299	10/22/2003	Napoleone Ferrara	11669.0139USC1	9503

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,299	FERRARA ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8 and 12-37* is/are pending in the application.

4a) Of the above claim(s) *13-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-8, 12 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 6-8, and 12-37 are pending.

2. Claims 13-25 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

3. Claims 1, 6-8, 12 and newly added claims 26-37, drawn to EG-VEGF polypeptide and chimeric polypeptide, are being acted upon in this Office Action.

4. In view of the amendment filed 7/5/07, the following rejections remain.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 7, 12, 30, 32, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any isolated EG-VEGF polypeptide "having at least 95% identity" to amino acid residues 20 to 105 of SEQ ID NO: 2 and (2) any isolated EG-VEGF polypeptide comprising "at least 95% identity" to SEQ ID NO: 2.

Claims 1 and 7 encompass any isolated EG-VEGF polypeptide having at least about 95% identity to amino acid residues 20 to 105 of SEQ ID NO: 2 or comprising at least 95% identity to SEQ ID NO: 2 without any function.

The specification discloses only *one* isolated human EG-VEGF polypeptide comprising *the* amino acid sequence of SEQ ID NO: 2 wherein the polypeptide promotes proliferation of

adrenal cortex-derived capillary endothelial cells, see page 10, Figure 13A. The secreted or mature EG-VEGF polypeptide comprises amino acid residues 20 to 105 of SEQ ID NO: 2.

The specification has not adequate described which amino acids within the full-length sequence of SEQ ID NO: 2 or the amino acid residues 20 to 105 of SEQ ID NO: 2 to be substitute, deleted, added and/or combination thereof such that the EG-VEGF variant still maintains its structure and function such as promoting proliferation of adrenal cortex-derived capillary endothelial cells.

Deleting the functional language in claims 1 and 7 rendering the claims having structure without function.

There is not a single sequence comprising an amino acid sequence having at least 95% sequence identity with the amino acid sequence comprising SEQ ID NO: 2 or having at least 95% sequence identity with the amino acid sequence of residues 20 to 105 of SEQ ID NO: 2. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is sufficient to support the claim.

Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001 as well as the USPTO revised written description guidelines training materials, see Example 14 in particular.

Applicants' arguments filed 7/5/07 have been fully considered but are not found persuasive.

Applicants' position is that Claim 1 has been amended to recite an isolated EG-VEGF polypeptide having at least 95% amino acid sequence identity with the amino acid sequence of residues 20 to 105 of SEQ ID NO:2. The claim encompasses 4 or fewer amino acid substitutions, mutations, and/or deletions in the sequence defined by residues 20-105 of SEQ ID NO:2. The specification describes techniques and guidelines for making EG-VEGF variants, including amino acid sequence comparison methods and exemplary and preferred amino acid substitutions (see specification at page 14, line 17 to page 16, line 15; page 30, line 22 to page 33, line 23; and Table 1 at page 32). Example 1 describes how to isolate

cDNA clones encoding EG-VEGF, including the signal sequence finding algorithm used to identify cDNA clones. Example 2 describes how to use DNA comprising the coding sequence of mature EG-VEGF, for example, as a probe to screen for homologous DNA molecules encoding, for example, naturally occurring variants of EG-VEGF. Examples 3-6 describe how to express EG-VEGF in cells. Example 7 describes how to make antibodies that specifically bind EG-VEGF. Example 8 describes how to purify EG-VEGF using anti-EG-VEGF antibodies.

The level of skill in the art is high and advanced. In view of the description provided in the specification and the high level of skill in the art, Applicants submit one of skill in the art would have recognized the spectrum of EG-VEGF polypeptides encompassed by the claims.

The Office Action alleges the specification has not identified which amino acids within the one or more internal domains of the full-length sequence SEQ ID NO:2 or the mature sequence (amino acid residues 20-105 of SEQ ID NO:2) can be substituted, deleted, and/or added such that the resulting modified EG-VEGF polypeptide functions to promote proliferation of ACE cells. Without such disclosure, the Office Action alleges one of skill in the art would not be able to reasonably conclude that the inventor had possession of the claimed invention. Applicants respectfully do not agree.

Applicants direct the Examiner's attention to Example 14 of the USPTO Revised Written Description Guidelines Training Materials. Example 14 outlines a written description analysis of a polypeptide claim that satisfies the requirement under 35 U.S.C. § 112, first paragraph. The claim in Example 14 is directed to a genus of polypeptides having at least 95% identity to a reference sequence (SEQ ID NO:3) and a specific activity.

In response, deleting the functional language in claims 1 and 7 rendering the claims and dependent claims having structure without function. Examiner directs the Applicants' attention to Example 14 of the USPTO Revised Written Description Guidelines Training Materials. Example 14 outlines a written description analysis of a polypeptide claim that satisfies the requirement under 35 U.S.C. § 112, first paragraph. The claim in Example 14 is directed to a genus of polypeptides having at least 95% identity to a reference sequence (SEQ ID NO:3) and a *specific activity*.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 6-8, 12, and 26-37 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,119,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claims 1 and 26 of instant application recite an isolated EG-VEGF polypeptide comprising at least 95% amino acid sequence identity with the amino acid residues 20 to 105 of SEQ ID NO: 2, wherein the polypeptide promotes proliferation of adrenal cortex-derived capillary endothelial cells (genus). Claims 6 and 27 of instant application recite the isolated EG-VEGF polypeptide comprising amino acid residues 20 to 105 of SEQ ID NO: 2, wherein the polypeptide promotes proliferation of adrenal cortex-derived capillary endothelial cells (genus). Claims 7 and 28 of instant application recite the isolated EG-VEGF polypeptide wherein the polypeptide comprises at least 95% identity to SEQ ID NO: 2 and wherein the polypeptide promotes proliferation of adrenal cortex-derived capillary endothelial cells (genus). Claims 8 and 29 of instant application recite an isolated EG-VEGF polypeptide comprising the amino acid residues 20 to 105 of SEQ ID NO: 2, wherein the polypeptide promotes proliferation of adrenal

cortex-derived capillary endothelial cells (species). Claim 12 of instant application recites the isolated EG-VEGF polypeptide mentioned above is a human sequence.

Claim 1 of the '177 patent recites an isolated polypeptide comprising: (a) the amino acid sequence of the polypeptide of SEQ ID NO: 371; (b) the amino acid sequence of the polypeptide of SEQ ID NO: 371; lacking its associated signal peptide; (c) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203091. The polypeptide comprising SEQ ID NO: 371 is 100% identical to the EG-VEGF comprising SEQ ID NO: 2 and inherently promotes proliferation of adrenal cortex-derived capillary endothelial cells. The term "comprising" is open-ended. It expands the residues 20 to 105 of SEQ ID NO: 2 to include the signal peptide to include the polypeptide comprising SEQ ID NO: 371 of the '177 patent. The polypeptide comprising SEQ ID NO: 371 is a human sequence. The polypeptide of SEQ ID NO: 371 lacking its associated signal peptide (claims 1(b) and 2 of the '177 patent) is the same polypeptide having 100% sequence identity with the amino acid residues 20 to 105 of SEQ ID NO: 2 of instant application. Issuance of a patent to instant application (genus) would include the polypeptide of the '371 patent (species).

Newly added claims 30-37 of instant application recite a chimeric polypeptide comprising the polypeptide mentioned above fused to a heterologous polypeptide (genus), heterologous polypeptide such as HIS tag or Fc portion of an immunoglobulin (species).

Claim 3 of the '177 patent recites a chimeric polypeptide comprising a polypeptide according to claim 1 fused to a heterologous polypeptide. Claim 4 of the '177 patent recites the chimeric polypeptide of claim 3, wherein said heterologous polypeptide is an epitope tag or an Fc region of an immunoglobulin (species). The issuance of a patent to instant application would include the species of polypeptide and chimeric polypeptide of the issuance patent.

Applicant's request of the rejection be held in abeyance until allowable subject matter is indicated is acknowledged.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

12. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 14, 2007

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